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United Nations Conference on Trade and Development

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Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices
Geneva, 6–10 July 2015
Item 4 of the provisional agenda
Adoption of the agenda and organization of work of the Conference

Annotated provisional agenda and organization of work

I. Provisional agenda

1. Opening of the Conference.[1]
2. Election of the President and other officers.
3. Adoption of the rules of procedure.
4. Adoption of the agenda and organization of work of the Conference.
5. Credentials of the representatives to the Conference:
   (a) Appointment of a Credentials Committee;
   (b) Report of the Credentials Committee.
6. Review of all aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices:
   (a) Review of application and implementation of the Set;
   (b) Consideration of proposals for the improvement and further development of the Set, including international cooperation in the field of control of restrictive business practices.
7. Other business.
8. Adoption of the report of the Conference.

[1] Conference website: http://unctad.org/en/pages/MeetingDetails.aspx?meetingid=609.

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II. Annotations

1. The General Assembly, in paragraph 23 of its omnibus trade resolution 65/142, adopted on 2 February 2011, decided to convene a Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices. The Conference is to be held under the auspices of UNCTAD in Geneva, Switzerland, in 2015. The Intergovernmental Group of Experts on Competition Law and Policy, at its fourteenth session, which took place from 8 to 10 July 2014, acted as the preparatory body for the Conference and approved the Provisional agenda for the Seventh Review Conference. The report of the Intergovernmental Group of Experts on Competition Law and Policy at its fourteenth session is contained in document TD/B/C.I/CLP/34.

Item 1
Opening of the Conference

2. The Conference will be opened at 10 a.m. on Monday, 6 July 2015, by the Secretary-General of UNCTAD or by his representative.

Item 2
Election of the President and other officers

3. Rule 7 of the provisional rules of procedure of the Conference (TD/RBP/CONF.7/9) provides that the Conference shall elect, with due regard to equitable geographical distribution, a President, a Rapporteur and Vice-Presidents. The President, the Vice-Presidents and the Rapporteur shall constitute the Bureau of the Conference.

Item 3
Adoption of the rules of procedure

4. The provisional rules of procedure of the Conference, as adopted by the previous six Conferences, are contained in document TD/RBP/CONF.7/9.

Documentation

TD/RBP/CONF.7/9	Provisional rules of procedure of the Conference

Item 4
Adoption of the agenda and organization of work of the Conference

5. The text of the provisional agenda, as set out in chapter I above, was approved by the Intergovernmental Group of Experts on Competition Law and Policy at its fourteenth session (see TD/B/C.I/CLP/34, annex I).

Regional group meetings

6. Appropriate time and facilities shall be made available daily throughout the duration of the Conference for regional group meetings.

Facilities available

7. There will be interpretation facilities available from 10 a.m. to 1 p.m. in the mornings and from 3 p.m. to 6 p.m. in the afternoons throughout the duration of the Conference.

Work of the Conference

8. The Conference has at its disposal five working days from 6 to 10 July 2015. It is suggested that the first meeting, on 6 July, be devoted to procedural matters, namely items 1 to 5 (a) of the provisional agenda, as well as to a high-level segment, interactive debate and opening statements, and that the last meeting, on 10 July, be devoted to items 5 (b) to item 8. The remaining meetings would be devoted to the substantive item 6 and to the informal consultations. A proposed programme of work is provided in the annex to this document.

Documentation

TD/RBP/CONF.8/1	Annotated provisional agenda and organization of work

Item 5
Credentials of the representatives to the Conference

9. Rule 5 of the provisional rules of procedure provides that a Credentials Committee shall be appointed at the beginning of the Conference. It shall examine the credentials of representatives and report to the Conference.

(a) Appointment of a Credentials Committee

(b) Report of the Credentials Committee

Item 6
Review of all aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices

(a) Review of application and implementation of the Set

10. In acting as the preparatory body for the Seventh Review Conference, the Intergovernmental Group of Experts on Competition Law and Policy, at its fourteenth session on 8–10 July 2014, invited the Secretary-General of UNCTAD to prepare an assessment of the operation of the United Nations Set (see TD/B/C.I/CLP/34, agreed conclusions).

11. The assessment prepared by the UNCTAD secretariat is contained in document TD/RBP/CONF.8/2. In addition, Governments will be invited to present their views on the implementation of the United Nations Set under this agenda item. Written contributions of the participants will be made available on the Conference website.[2]

12. The following documents will be submitted:

(a) Assessment of the application and implementation of the Set (TD/RBP/CONF.8/2);

(b) An updated version of chapter I the Model Law on Competition (TD/RBP/CONF.8/L.1);

(c) An updated version of chapter IV the Model Law on Competition (TD/RBP/CONF.8/L.2);

[2] http://unctad.org/en/pages/MeetingDetails.aspx?meetingid=609.

(d) An updated version of chapter VIII the Model Law on Competition (TD/RBP/CONF.8/L.3);

(e) An updated version of chapter XI the Model Law on Competition (TD/RBP/CONF.8/L.4);

(f) An updated version of chapter XIII the Model Law on Competition (TD/RBP/CONF.8/L.5).

(b) Consideration of proposals for the improvement and further development of the Set, including international cooperation in the field of control of restrictive business practices

13. In order to assist the Seventh Review Conference in its work, the Trade and Development Commission at its seventh session, to be held from 18 to 22 May 2015, will welcome regional initiatives in convening preparatory meetings for the Seventh Review Conference, with the assistance of the UNCTAD secretariat, focusing on reviewing the respective experiences in the implementation of the United Nations Set.

14. The Intergovernmental Group of Experts on Competition Law and Policy, at its fourteenth session, further recommended that the Seventh Review Conference consider the issues related to the better implementation of the Set as set out below.

15. Accordingly, the Conference will hold informal consultations to exchange views on these important competition policy issues. Governments are invited to submit short notes on their interventions in advance to the UNCTAD secretariat in order for these to be reproduced and made available to participants.

16. The Intergovernmental Group of Experts at its fourteenth session also requested the UNCTAD secretariat to prepare five clusters of issues under separate sessions for consideration by the Seventh Review Conference:

(a) Ways and means to strengthen competition agencies in order to better deliver competition policy enforcement and advocacy;

(b) Feedback from recently peer-reviewed countries with competition agencies on enforcement and changes since the peer reviews;

(c) The role of competition policy in promoting sustainable and inclusive growth;

(d) International cooperation in merger cases as a tool for effective enforcement of competition law;

(e) The benefits and the role of competition for consumers in the pharmaceutical sector.

17. Accordingly, the Conference will have before it a report on each of the topics listed above. The following documents will be submitted:

(a) The role of competition policy in promoting sustainable and inclusive growth (TD/RBP/CONF.8/6);

(b) The role of competition in the pharmaceutical sector and its benefits for consumers (TD/RBP/CONF.8/3);

(c) Ways and means to strengthen competition law enforcement and advocacy (TD/RBP/CONF.8/5);

(d) International cooperation in merger cases as a tool for effective enforcement of competition law (TD/RBP/CONF.8/4);

(e) Feedback for improving the efficiency of the application of UNCTAD voluntary peer reviews (TD/RBP/CONF.8/10);

(f) Capacity-building and technical assistance on competition and consumer protection law and policy: Review and outlook (TD/RBP/CONF.8/7).

18. The Conference will also hold voluntary peer reviews on the competition law and policy of Albania, and of Fiji and Papua New Guinea. As basic documents for the peer reviews, the Conference will have before it four reports as called for by the fourteenth session of the Intergovernmental Group of Experts on Competition Law and Policy:

(a) An overview of the Voluntary Peer Review on Competition Law and Policy of Albania (TD/B/RBP/Conf.8/8);

(b) A report of the Voluntary Peer Review on Competition Law and Policy of Albania (UNCTAD/DITC/CLP/2015/1);

(c) An overview of the Voluntary Peer Review on Competition Law and Policy of Fiji and Papua New Guinea (TD/B/RBP/CONF.8/9);

(d) A report of the Voluntary Peer Review on Competition Law and Policy of Fiji and Papua New Guinea (UNCTAD/DITC/CLP/2015/2).

19. Delegates wishing to participate in the peer reviews on the competition law and policy of Albania, and Fiji and Papua New Guinea are invited to inform the UNCTAD secretariat in advance of the Conference so that the programme for the peer review can be finalized in time and participants have adequate time to prepare themselves for the consultations.

Item 7
Other business

19. The Conference shall, among other issues, discuss and adopt a provisional agenda for the fifteenth session of the Intergovernmental Group of Experts on Competition Law and Policy.

Item 8
Adoption of the report of the Conference

20. Rule 52 of the provisional rules of procedure states that the Conference may recommend to the General Assembly the adoption of amendments to the United Nations Set of Principles and Rules. Rule 52 of the provisional rules of procedure also provides that the Conference shall adopt a report on its proceedings. The final report of the Seventh Review Conference will be submitted to the United Nations General Assembly through the Trade and Development Board.

Annex

Proposed draft work programme

	Monday 6 July	*Tuesday 7 July*	*Wednesday 8 July*	*Thursday 9 July*	*Friday 10 July*
10 a.m.–1 p.m.	**Opening plenary** Inaugural ceremony followed by • Items 1–5 (a) • High-level segment followed by interactive debate and general statements	**Item 6 (a) and (b)** – Ways and means to strengthen competition agencies in order to better deliver competition policy enforcement and advocacy	**Item 6 (a) and (b)** – The benefits and the role of competition for consumers in the pharmaceutical sector	**Item 6 (a) and (b)** – Report of the work of the ad hoc expert meeting on the interface between consumer and competition policies, including proposal for the revision of the United Nations Guidelines for Consumer Protection	**Item 6 (a) and (b) (cont'd)** – Capacity-building activities – Evaluation of UNCTAD voluntary peer reviews: Feedback of the peer review process
15.00–18.00	**Item 6 (a) and (b)** – Voluntary peer review on competition law and policy: Fiji and Papua New Guinea	**Item 6 (a) and (b)** – Voluntary peer review of competition law and policy: Albania	**Item 6 (a) and (b)** – International cooperation in merger cases as a tool for effective enforcement of competition law: An updated review of capacity-building and technical assistance on competition law and policy	**Item 6 (a) and (b)** – Review of the Implementation of the United Nations Set of Principles on Competition Policy – Consultations on the revised chapters I, IV, VIII, XI and XIII of the UNCTAD Model Law on Competition	**Closing plenary** **Item 5 (b)** – Report of the Credentials Committee **Item 6** – Adoption of the draft resolution of the Conference **Item 7** – Other business – Adoption of the provisional agenda for the Intergovernmental Group of Experts, fifteenth session **Item 8** – Adoption of the report of the Conference

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Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices
Geneva, 6–10 July 2015
Item 6 (a) of the provisional agenda
Review of application and implementation of the Set

Assessment of the application and implementation of the Set

Note by the UNCTAD secretariat

Executive summary

This note reviews major developments that have taken place at the national, regional and multilateral levels in the field of competition law and policy, particularly since November 2010, when the Sixth United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices was held. The note then reviews in chapter I the operation of the Set in the field of competition law and policy, looking at its main provisions and evaluating the extent to which they have been implemented to date. An evaluation is made of progress in implementation by States members of UNCTAD and by the Intergovernmental Group of Experts on Competition Law and Policy of the resolution adopted by the Sixth Review Conference, drawing attention to technical assistance and UNCTAD voluntary peer reviews. In chapter II, details are provided of developments in international cooperation based on UNCTAD studies conducted for annual meetings of the Intergovernmental Group of Experts since 2010. Finally, in chapter III, the note outlines possible activities in the field of competition and consumer protection policy that the Seventh Review Conference might wish to launch in the next five years.

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Introduction

1. The General Assembly, in its omnibus trade resolution 65/142, paragraph 23, adopted on 20 December 2010, reaffirmed the fundamental role of competition law and policy in sound economic development and took note of the final report of the Sixth United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices.[1]

2. The Set was adopted 35 years ago and has since been the only multilateral framework on competition. Competition law and policy continues to attract attention at national, regional and multilateral levels. At the national level, 122 countries, including developing countries and countries with economies in transition, have adopted competition laws.

3. Since the Sixth Review Conference, which was held in November 2010, six developing countries, including three least developed countries, have introduced competition laws. At the regional level, many groupings of States are in the process of implementing regional competition rules. The Competition Commission of the Common Market for Eastern and Southern Africa began implementing its competition regulations and rules on 14 January 2013. The West African Economic and Monetary Union is reforming its regional legal framework on competition, which was adopted in 2002, to achieve a reasonable balance between national and regional enforcement.

4. The International Competition Network, Organization for Economic Cooperation and Development and UNCTAD have been very active in disseminating competition law and policy principles throughout the world, while national competition authorities have responded to these efforts, both bilaterally and though cooperation with these organizations.

5. In the period between the Sixth Review Conference and January 2015, four sessions of the Intergovernmental Group of Experts on Competition Law and Policy, three Ad Hoc Experts Meetings on Consumer Protection and one Ad Hoc Expert Meeting on the Role of Competition Law and Policy in Fostering Sustainable Development and Trade through the Enhancement of Domestic and International Competitiveness of Developing Countries took place at UNCTAD. The fourteenth session of the Intergovernmental Group of Experts, held in July 2014, acted as a preparatory meeting for the Seventh Review Conference.

6. In April 2012, UNCTAD XIII took place in Doha, Qatar. The Conference, which examined development-centred globalization – towards inclusive and sustainable growth and development – considered the role of competition law and policy in this context and agreed in the Doha Manar that the "development of competition policies remains important for fostering a competitive environment and preventing anticompetitive practices" (paragraph 10).

7. The Doha Mandate recognizes that the "objective of competition policy is to create and maintain a competitive environment by eliminating anticompetitive practices", and encourages member States to "consider establishing competition laws and frameworks in coherence with their national development strategies" (paragraph 50). The Mandate states that UNCTAD should "conduct analysis and research and help developing countries and countries with economies in transition to formulate and implement competition and consumer protection policies, promote the sharing of best practices, and carry out peer reviews with regard to the implementation of such policies" (paragraph 56(m)).

[1] TD/RBP/CONF.7/11.

8. It is important to note that competition policy was included among the priorities of UNCTAD in contributing to making globalization more efficient and more equitable. The Set aims to achieve greater efficiency in international trade and development in line with national economic and social policies, and eliminate disadvantages to trade and development, which may result from anticompetitive business practices. It seeks to "protect and promote social welfare... and the interest of consumers". The Set is entitled "Set of Equitable Principles and Rules", in particular because it endorses the principle of "Preferential or Differential Treatment for developing countries" as embodied in Section C.

I. Implementation of the Set

A. Objectives of the Set

9. Objective No. 1 of the Set – "to ensure that restrictive business practices do not impede or negate the realization of benefits that should arise from the liberalization of tariff and non-tariff barriers affecting world trade, particularly those affecting the trade and development of developing countries" – is of particular relevance today, as globalization is rapidly expanding and more and more questions are being raised concerning the effects of economic recession, especially with respect to the relative roles of Governments and markets.

10. With respect to Objective No. 2 – "to attain greater efficiency in international trade and development, particularly that of developing countries, in accordance with national aims of economic and social development and existing economic structures, such as through: (a) The creation, encouragement and protection of competition; (b) Control of the concentration of capital and/or economic power; (c) Encouragement of innovation" – the results have been encouraging. Since the Sixth Review Conference, many developing counties and countries with economies in transition have shown great interest in competition policy and enacted relevant legislation. In this period, eight countries and/or territories adopted new competition laws, namely Afghanistan (2010), Fiji (2010), Ecuador (2011), Bangladesh (2012), Hong Kong, China (2012), Ethiopia (2013), Paraguay (2013) and Brunei Darussalam (2015). Cambodia, the Lao People's Democratic Republic, Myanmar and the Philippines are currently drafting competition laws (see http://www.asean.org/communities/asean-economic-community/category/competition-policy). In the period under review, many countries substantially reformed their competition laws, including Albania (2010), Australia (2010), Kenya (2010), Mongolia (2010), Zambia (2010), Kyrgyzstan (2011), Malta (2011), Brazil (2012), Moldova (2012), Montenegro (2012), Ireland (2014) and Mexico (2014).

11. It should be noted that, in line with the request made by the fourteenth session of the Intergovernmental Group of Experts on Competition Law and Policy in its agreed conclusions, the secretariat is making available to the Seventh Review Conference a report on the role of competition policy in promoting sustainable and inclusive growth.[2] The report addresses the ways in which competition policy and law may contribute to sustainable and inclusive development and gives examples from the laws and policies of various countries.

12. Objective No. 3 – "to protect and promote social welfare in general and, in particular, the interests of consumers in both developed and developing countries" – is receiving increased attention in many countries worldwide. Reflecting this, the Sixth

[2] TD/RBP/CONF.8/6.

Review Conference decided that UNCTAD should respond to calls from member States to undertake consultations on a revision of the United Nations Guidelines on Consumer Protection. The first Ad Hoc Expert Group Meeting on Consumer Protection, held in July 2012, requested that UNCTAD prepare an implementation report on the Guidelines. This report concluded that, since 1985, the Guidelines have been widely implemented by Member States of the United Nations.[3] National contributions (over 50) to this implementation assessment showed that all areas of the current Guidelines remained valid and useful. In addition, new challenges to consumer protection were identified, namely e-commerce and financial services, and there was interest in additional issues that merited wider consultations and the implementation and monitoring of the Guidelines.

13. The second Ad Hoc Expert Group Meeting on Consumer Protection, held in July 2013, reviewed the implementation report. During the discussions, several areas were identified for incorporation in any future revision, particularly areas where substantive progress has already been made by other organizations, such as the Organization for Economic Cooperation and Development and the Group of 20, and where substantial consensus among Member States of the United Nations has already been achieved. The following two areas were identified in particular: e-commerce (Organization for Economic Cooperation and Development Guidelines for Consumer Protection in the Context of Electronic Commerce (1999), currently under revision (due in 2016)); and financial services (Group of 20 High-level Principles on Financial Consumer Protection (2012)). The meeting also identified a range of other issues that would merit further discussion before inclusion in any revision, namely data protection, abusive advertising, cross-border trade, public services, access to knowledge, collective redress mechanisms, tourism, energy, transport and housing. Finally, many experts also called for an implementation and control mechanism for the United Nations Guidelines on Consumer Protection.

14. As a framework to explore these issues, a proposal was accepted to establish four working groups on the following themes: e-commerce (chaired by France); financial services (chaired by Malaysia); implementation of the United Nations Guidelines on Consumer Protection (chaired by Gabon); and other issues (chaired by Brazil and Germany). The second Ad Hoc Expert Group Meeting further agreed that the secretariat would prepare a report on these issues to be submitted to the Seventh Review Conference for inclusion in a possible future revision of the United Nations Guidelines on Consumer Protection, in close collaboration with the chairs of the working groups.

15. In collaboration with the chairs of the four working groups, the Chair of the second Ad Hoc Expert Group Meeting (France) and the Coordinator of the Working Groups (Portugal), the secretariat prepared questionnaires for each working group, which were then disseminated in order to solicit views, concerns, best practices and recommendations from member States and other relevant stakeholders. The responses to the questionnaires formed the basis of a report on modalities for the revision of the United Nations Guidelines for Consumer Protection, which outlined findings and trends and highlighted key issues as expressed by member States and relevant stakeholders. Throughout 2013 and 2014, UNCTAD undertook regional consultations on the margins of regional gatherings of consumer protection experts in Colombia, the Dominican Republic, France, Mexico, Panama, Sweden, Switzerland, Thailand and Tunisia.

16. The report on modalities for the revision of the United Nations Guidelines on Consumer Protection served as the basis for discussions at the third Ad Hoc Expert Group Meeting on Consumer Protection, held in January 2015. Participants held detailed discussions on a draft resolution, and consultations on the draft continued with all

[3] TD/B/C.I/CLP/23.

stakeholders at various meetings in the following months, in preparation for submission of the draft resolution to the Seventh Review Conference.

B. The development dimension

17. Section C of the Set, on multilaterally agreed equitable principles for the control of restrictive business practices, recognizes the possibility for national legislation to exclude certain sectors from the scope of national competition law (paragraph 6) and provides for "preferential or differential treatment for developing countries" in order that States take into account the "development, financial and trade needs of developing countries, in particular of the least developed countries, for the purposes especially of developing countries in: (a) Promoting the establishment or development of domestic industries and the economic development of other sectors of the economy; and (b) Encouraging their economic development through regional or global arrangements among developing countries" (paragraph 7).

18. In the long term, full competition is essential for the competitiveness of firms and industries. There has been widespread adoption of reforms promoting competition in developing countries and countries with economies in transition. In recent years, there has been substantial convergence in the competition policies followed by different countries, although there remain substantial differences between them.

19. A degree of flexibility for countries newly opening their markets is therefore fully in line with this provision of the Set. Developing countries concerned with the risk of eliminating local industry as a result of the sudden opening of specific markets to strong competition should therefore be in a position to take a more flexible, gradualist approach in order to ensure that liberalization takes place when their industries are more efficient and able to compete. It is not in the interest of countries to keep afloat industries that are never going to be viable without protection and subsidies, thus distorting the allocation of scarce resources.

20. In 2010, UNCTAD created the Research Partnership Platform, an initiative that aims at contributing to the development of best practices in the formulation and effective enforcement of competition and consumer protection laws and policies so as to promote development. The partnership brings together research institutions, universities, competition authorities, business and civil society, providing a platform where they can undertake joint research and other activities with UNCTAD, disseminate the results of their own work and exchange ideas on issues and challenges in the areas of competition and consumer protection, particularly those faced by developing countries and countries with economies in transition. The role of UNCTAD is to facilitate and provide guidance on research and analysis and other activities to be undertaken by members of the platform. UNCTAD benefits from the research findings when responding to the challenges faced by developing countries through its technical assistance and capacity-building activities.

21. The first meeting of the Research Partnership Platform in 2010 included 10 participants, while the fifth meeting in 2014 involved close to 100 participants. The fifth meeting also saw the launch of the UNCTAD Research Partnership Platform publication series.[4] The Platform currently hosts as partners over sixty institutions, consisting of research institutes, universities, non-governmental organizations, corporate affiliates and

[4] UNCTAD, 2014, *Competitive neutrality and its application in selected developing countries* (Geneva, United Nations publication), available at http://unctad.org/en/PublicationsLibrary/ditcclpmisc2014d1_en.pdf.

competition agencies. The next step in the evolution of the Platform is to capture sources of funding in order to cater for its rapid expansion and fulfil the entirety of its mandate, including the joint organization of conferences and seminars, the joint organization of training courses and workshops in developing countries where UNCTAD conducts capacity-building projects and the joint design of training modules and pedagogical materials on specific topics related to competition and consumer protection.

22. The interface between competition and development policies has been a perennial topic for the Intergovernmental Group of Experts on Competition Law and Policy. The Group considered certain aspects of the interface including, in 2012, cross-border anticompetitive practices and the challenges for developing countries and countries with economies in transition and, in 2013, the impact of cartels on the poor. In addition, UNCTAD issued publications in the period 2011–2014 with a focus on this interface, including on competition in the economy of Cameroon, competition issues in the transport sector in Lesotho, competition issues in the tobacco industry of Malawi and competition issues in the economy of Mozambique, as well as the first publication in the UNCTAD Research Partnership Platform publication series (see http://unctad.org/en/Pages/DITC/CompetitionLaw/Competition-Law-and-Policy.aspx).

23. In July 2014, preceding the fourteenth session of the Intergovernmental Group of Experts on Competition Law and Policy, UNCTAD organized an Ad Hoc Expert Meeting on the Role of Competition Law and Policy in Fostering Sustainable Development and Trade through the Enhancement of Domestic and International Competitiveness of Developing Countries. In consideration of the fact that growth and development depends on efforts carried out in many different fields and that there are close linkages between competition, trade, intellectual property and improved governance policies, UNCTAD invited officials from the Organization for Economic Cooperation and Development, World Intellectual Property Organization and World Trade Organization to discuss issues including innovation, competitive neutrality, improved governance policies, trade liberalization, global value chains and intellectual property rights.

C. The main anticompetitive practices

24. Section D of the Set, on Principles and Rules for enterprises, including transnational corporations, contains the core anticompetitive practices that should be refrained from by enterprises "engaged on the market in rival or potentially rival activities" when "through an abuse or acquisition and abuse of a dominant position of market power, they limit access to markets or otherwise unduly restrain competition" (paragraphs 3 and 4). The treatment of horizontal and vertical restraints, as well as dominance and abuse of dominant market power, is further elaborated in the model law on competition prepared by UNCTAD. In line with the request of the Sixth Review Conference, the commentary to the model law is being revised periodically in light of legislative developments and comments made by member States for consideration by subsequent sessions of the Intergovernmental Group of Experts on Competition Law and Policy and Review Conferences. In this context, revisions to chapters I, IV, VIII, XI and XIII of the model law have been submitted to the Seventh Review Conference.

25. Section E of the Set, on Principles and Rules for States at National, Regional and Subregional levels, and Section F, on international measures, complement each other, as Section E states that "States should, at the national level or through regional groupings, adopt, improve and effectively enforce appropriate legislation and implementing judicial and administrative procedures" (paragraph 1). The provisions calling for exchanges of information and cooperation in Section E are complemented by those in Section F, which calls for "work aimed at achieving common approaches" (paragraph 1), consultations

among States (paragraph 4), continued work by UNCTAD on the elaboration of a model law or laws (paragraph 5) and technical assistance and advisory and training programmes (paragraph 6).

D. Efforts made by member States and regional groupings

26. As indicated in the introduction, in the period since the Sixth Review Conference, there has been considerable interest on the part of developing and least developed countries in drafting national competition laws. Seven countries adopted new competition laws and more than 12 countries reformed existing legislation in the period under review. Many more are preparing domestic legislation.

27. At the regional level, some groupings have begun to implement regional competition rules and/or engage in cooperation agreements for more effective competition law enforcement. Common approaches and the harmonization of legislation are on the increase, largely as a result of constructive exchanges of experiences and consultations that take place in bilateral, regional and multilateral forums, such as the International Competition Network, Intergovernmental Group of Experts on Competition Law and Policy and Organization for Economic Cooperation and Development. The regional enforcement of competition policy in Central America is considered in the box.

Towards a mechanism for regional enforcement of competition policy in Central America

Under the regional component of the second phase of the technical assistance programme on competition and consumer protection policies for Latin America (COMPAL), UNCTAD prepared a study on the regional enforcement of competition policy in Central America, covering Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama. The study focuses on competition problems in three selected economic sectors in the region, namely banking, medicinal drugs and international passenger air transport. For each of these sectors, the study determines that a coordinated effort by the region's competition authorities would provide many advantages over the isolated efforts of each national competition authority. Based on these findings, the study proposes that cooperation between the region's competition authorities be strengthened.

The study identifies some regulatory problems in the banking sector that may block market entry by potential new competitors or limit the ability of some to compete with others by imposing discriminatory treatment. Specific structural weaknesses (lack of market development and related financial instruments or alternative technologies) that could restrict the contestability of the markets in which commercial banks operate are also identified. The work of competition authorities in this sector is essential in advocating for regulatory changes to improve competitive conditions and prevent anticompetitive practices.

In the pharmaceutical sector, specific national regulations concerning the authorization of drugs or drug production and distribution, and others that restrict activities or limit parallel imports and intraregional trade in generic drugs, may limit competition in these markets. With respect to public procurement, the study notes that direct purchase abuse should be prevented, truly competitive tenders should be promoted (joint price negotiating in the Central American region is a good initiative) and the necessary mechanisms be put in place for detecting bid-rigging practices. In addition, competition authorities need to take action against anticompetitive practices in the form of price fixing or market-sharing agreements, exclusivity contracts in vertical relationships and practices such as bundled pricing, predatory behaviour and loyalty discounts by companies with market power.

In the passenger air transport sector, international air fares between Central American countries are too high for most of the population, significantly impacting the ability of people to move around the region. The study emphasizes that sector is clearly dominated by two major companies, which operate routes between the region's cities as a monopoly or duopoly. Although the problem may partially be structural, regulations and administrative practices tend to protect the installed operators against potential entrants. Moreover, airports – essential facilities for the activity – require investment for expanding and modernizing, along with clear, pro-competitive policies for allocating existing capacity. Other types of entry barriers may arise through the strategic behaviour of incumbent operators. The study determines that competition authorities need to pay special attention to agreements between airlines or between airlines and travel agencies.

In all three sectors, competition authorities need to review mergers and acquisitions that might be harmful for competition.

The competition-related problems identified by the study in each sector and the remedies proposed for resolving them require joint and coordinated efforts by national competition authorities. Regional cooperation on competition issues therefore needs to be strengthened. The study recommends a mechanism for regional enforcement of competition policy that comprises national authorities, in order to take advantage of their knowledge and experience. A set of regional rules and regulations needs to be developed for establishing the necessary coordination mechanisms. The model proposes that national competition authorities in the region jointly address competition problems with a regional scope, and could improve the efficacy and efficiency of the work of authorities to the benefit of Central American consumers and be adopted in a relatively short period of time with limited financial resources.

Source: UNCTAD, forthcoming, *Towards a Mechanism for Regional Enforcement of Competition Policy in Central America*.

E. Substantive discussions of the Intergovernmental Group of Experts on Competition Law and Policy

28. The round table consultations that take place annually during sessions of the Intergovernmental Group of Experts on Competition Law and Policy have become an appreciated feature of UNCTAD's intergovernmental machinery. This function of the Intergovernmental Group of Experts was decided by the Third Review Conference, held in 1990 (paragraph 9 of the resolution adopted by the Review Conference). In the period under review, the Intergovernmental Group of Experts held round tables on the following issues:

(a) Foundations of an effective competition agency;

(b) The importance of coherence between competition policies and government policies;

(c) Competition policy and public procurement;

(d) Cross-border anticompetitive practices: The challenges for developing countries and countries with economies in transition;

(e) Effectiveness, capacity-building and technical assistance extended to young competition agencies: Needs and challenges related to human resources and knowledge management;

(f) Knowledge and human resource management for effective enforcement of competition law;

(g) Prioritization and resource allocation as a tool for agency effectiveness;

(h) Modalities and procedures for international cooperation in competition cases involving more than one country;

(i) The impact of cartels on the poor;

(j) Capacity-building and UNCTAD voluntary peer reviews as a capacity-building tool;

(k) The benefit of competition law for consumers;

(l) Informal cooperation among competition agencies on specific issues;

(m) Communication strategies of competition authorities as a tool for agency effectiveness;

(n) UNCTAD capacity-building activities on competition law and policy.

29. The conclusions of consultations among experts during the meetings of the Intergovernmental Group of Experts on Competition Law and Policy are recorded in the reports of the meetings, and are disseminated by UNCTAD through capacity-building activities in the field and reflected in the reports of voluntary peer reviews of competition law and policy.

F. Technical assistance

30. Despite a general widespread trend towards the adoption, reformulation and better implementation of competition and consumer protection laws and policies in developing countries and countries with economies in transition, many of these countries still do not have up-to-date competition and consumer protection legislation or adequate institutions for their effective enforcement, and rely to a large extent on UNCTAD capacity-building. In this regard, UNCTAD provides capacity-building and technical assistance on competition law and policy at national and regional levels.

31. At national levels, UNCTAD, with the support of donor countries, has assisted developing countries from all regions of the world, including a number of least developed countries, in designing and formulating their competition and consumer protection policies and legislation, setting up their competition agencies, raising public awareness of the benefits of competition law and policy and contributing to the creation of a competition culture.

32. At regional levels, UNCTAD assists in drafting and the implementation of regional competition and consumer protection legislation, developing frameworks for cooperation in competition law enforcement and organizes conferences, seminars and workshops for different beneficiaries, including judiciary and academia, aimed at contributing to capacity-building and regional cooperation in the area of competition.

33. UNCTAD extends capacity-building and technical assistance in the area of competition and consumer protection policy on request from countries and regional groupings based on their needs and resources available, including the following activities:

(a) Drafting competition and consumer protection policies, laws, regulations and implementation guidelines for countries or regional organizations;

(b) Assisting countries or regional organizations in revising their competition and consumer protection legislation based on best international practices;

(c) Providing advisory services for setting up or strengthening competition authorities;

(d) Training competition and consumer protection officials and competition case handlers;

(e) Organizing seminars on competition law for judiciary;

(f) Conducting studies on competition issues in certain sectors;

(g) Organizing advocacy workshops and seminars on competition and consumer protection issues;

(h) Facilitating voluntary peer reviews of the competition laws and policies of interested countries.

34. The direct beneficiaries of UNCTAD technical assistance programmes include government officials responsible for implementing competition and consumer protection laws and policies, officials of other relevant government bodies and sector regulators, the judiciary, business, consumer associations and academia.

35. UNCTAD capacity-building and training activities increased considerably in the period under review. This was due in part to the considerable interest demonstrated by member States, at both national and regional levels, as well as to the solidarity demonstrated by donors from many countries who made generous financial contributions and contributions in kind.

36. COMPAL is supported by the State Secretariat for Economic Affairs of Switzerland (see http://programacompal.org). Five Latin American beneficiary countries, namely the Plurinational State of Bolivia, Costa Rica, El Salvador, Nicaragua and Peru, benefited from this programme during its first phase (2005–2008). Under its second phase, COMPAL II (2009–2013), the number of beneficiary countries increased to 10, including Colombia, the Dominican Republic, Ecuador, Paraguay and Uruguay. Guatemala and Honduras participated in regional component activities of the programme using their own resources. COMPAL II created a well-functioning peer-learning process and a platform for regional cooperation, including the creation of an Advisory Group of Experts, a collegial body comprising former heads of competition and consumer protection agencies in the Latin American region. Following the successful implementation and impact of the first two phases, COMPAL III, initiated in early 2015, involves three additional countries, namely Argentina, Chile and Mexico.

37. In addition, in order to streamline the technical assistance activities of UNCTAD and increase their impact, a Global COMPAL strategy was launched by the Secretary-General of UNCTAD in 2014.[5] Following its adoption, the strategy was extended to countries in the Middle East and North Africa. The extension of the programme is funded by the Swedish International Development Cooperation Agency for an initial period of four years (2015–2019), and focuses on regional integration through the design and enforcement of competition and consumer rules as tools for inclusive and sustainable economic growth. The programme aims to enhance the capacities of countries in the Middle East and North Africa to adopt and implement effective competition and consumer policies, provide assistance to the private sector in order to create a competition culture without unnecessary bureaucratic burdens, develop a regional strategy to assist countries in the Middle East and North Africa in adopting competition neutrality frameworks and enforcing associated policies, respond to the specific needs and circumstances of different countries with tailored policy advice and capacity-building activities and effectively facilitate the ascension of new members to Global COMPAL. The beneficiaries are Algeria, Egypt, Lebanon, Jordan, Morocco, the State of Palestine, Tunisia and Yemen.

[5] For more information about the strategy, see TD/RBP/CONF.8/7.

38. As a follow-up to the peer review of the West African Economic and Monetary Union conducted in 2007, a memorandum of understanding was signed between UNCTAD and the Union in 2011 to implement the recommendations of the peer review. The Commission of the West African Economic and Monetary Union agreed to make a financial contribution to this three-year project. Since 2012, many activities have been carried out to facilitate the implementation of the competition rules of the Union by member States, including raising awareness of officials and the public on the benefits of competition, training competition officials, adapting the legislation of member States and adopting procedures at national and regional levels for effective implementation of community competition rules and reorganizing national competition institutions.

39. In addition, UNCTAD is implementing a technical assistance and capacity-building project for Zimbabwe to strengthen its competition regime, funded by the European Union and incorporated in its wider Trade and Private Sector Development Project. UNCTAD has recently begun working with the competition authority of Ethiopia in a capacity-building programme funded by Luxembourg. UNCTAD has also received requests from countries in the Middle East and will start a technical assistance and capacity-building programme in Qatar.

G. Voluntary peer reviews

40. UNCTAD launched its voluntary peer reviews of competition law and policy in 2005. The voluntary peer reviews are dedicated to enhancing the quality and effectiveness of the competition policy enforcement framework in member States, and involve the scrutiny of competition policy as embodied in competition law and consider the effectiveness of institutions and institutional arrangements in enforcing this law.

41. Since the Sixth Review Conference, voluntary peer reviews have been undertaken for 14 countries, namely Serbia (2011), Mongolia (2012), a tripartite peer review for the United Republic of Tanzania, Zambia and Zimbabwe (2012), Nicaragua (2013), Pakistan (2013), Ukraine (2013), Namibia (2014), the Philippines (2014), Seychelles (2014), Albania (2015), Fiji (2015) and Papua New Guinea (2015).

42. Beginning in 2005, the methodology used for evaluation of an authority involved conduct of a self-assessment system and the simultaneous selection of one or two independent experts to prepare an independent report based on the answers from questionnaires sent to authorities, analysis of the legal and institutional frameworks and interviews conducted with relevant officials in the country. This approach has evolved to include other forms of assessment, in order to provide more analytical elements that help focus on more unorthodox forms of the issues detected in State policies.

43. In 2012, UNCTAD first implemented a tripartite peer review covering three neighbouring countries, namely the United Republic of Tanzania, Zambia and Zimbabwe, using a different, more complex methodology whereby the countries did not perform a self-assessment but instead undertook mutual evaluations (each authority reviewed competition law and enforcement in one of the two neighbouring States). These national evaluations were supplemented by a comparative assessment report by an independent expert. The objectives of this new methodology were to provide greater insights and to seek synergies and solutions across competition systems in countries that are members of common regional arrangements and have close trade and economic relations.

44. Due to the success of the work carried out through the voluntary peer review process, requests have been received from member States for UNCTAD to expand this process to cover consumer protection issues. In response, UNCTAD will launch voluntary peer reviews of consumer protection law and policy in 2015. These reviews will scrutinize

consumer protection policy as embodied in law and consider the effectiveness of institutions and institutional arrangements in enforcing consumer protection law. Mexico has been accepted as the first member State to undergo this type of voluntary peer review.

45. With regard to a perspective of continuous improvement, UNCTAD has commissioned a report to evaluate the methodology and output of the peer review process over its 10-year existence. This report will be prepared by a number of independent experts, including individuals that have worked as independent experts on peer reviews, or heads of previously reviewed agencies. The strengths and weaknesses highlighted in the report will lead to specific recommendations for the further evolution of the voluntary peer review process, enabling future work by UNCTAD to be both of higher quality and more effective.

II. International cooperation

46. Cooperation in dealing with restrictive business practices is among the international measures provided for in the Set. The Sixth Review Conference decided that future sessions of the Intergovernmental Group of Experts on Competition Law and Policy should include international cooperation and networking as one of the four clusters of issues for informal consultations among participants on competition law and policy. It invited Governments, during future consultations in meetings of the Intergovernmental Group of Experts, to clarify the scope or application of their competition laws and policies, with a view to improving mutual understanding about substantive principles and procedures of competition law and policy. In the context of this exercise, Governments may wish to discuss the following: how the Set might be better implemented, particularly those provisions which have not been adequately implemented to date; techniques and procedures for detecting and sanctioning collusive tendering, including international cartels and other anticompetitive practices; and strengthening of information exchanges, consultations and cooperation in enforcement at the bilateral and regional levels, including subregional groupings.

47. Cooperation among competition agencies is an essential tool to address anticompetitive practices in the global economy. Communication among competition agencies throughout the world has improved considerably. Agencies have been employing various tools, ranging from formal agreements to informal communications to cooperate with each other.

48. First-generation bilateral agreements allowing exchange of information emerged first between developed countries, such as the Mutual Antitrust Enforcement Assistance Agreement (1999), between Australia and the United States of America. Cooperation under these agreements involves extensive reciprocal enforcement assistance between the parties, including exchanging confidential information subject to the consent of the investigated parties, taking individual testimonies and executing searches and seizures.

49. Second-generation agreements go beyond the previous ones in sharing confidential information. The first such agreement was signed between the European Union and Switzerland, and will take effect subject to approval by the European Parliament and the Swiss Parliament. This agreement allows parties, on request, to transmit confidential information for use as evidence, subject to certain safeguards, and even without the consent of the investigated party.

50. Most cooperation agreements limit the exchange of information to non-confidential information. This may be a significant drawback, especially in dealing with cross-border cartel cases, where confidential information located in a foreign jurisdiction may be pivotal to the success of enforcement.

51. Given the difficulties in engaging in formal cooperation arrangements, there has been an increase in informal cooperation in international cartel cases and mergers over the past decade. The tools for informal cooperation include bilateral memorandums of understanding, informal networking forums (e.g. the African Competition Forum and Euro-Mediterranean Competition Forum) and exchange of non-confidential case information. The European Commission has cooperated with other agencies in approximately 31 per cent of cartel investigations.[6] An UNCTAD study indicates that informal cooperation among competition authorities should not be underestimated.[7] If developing countries have no leniency programmes or formal cooperation agreements with other countries, informal cooperation may prove very effective in international cartel investigations. The study suggests that facilitating the exchange of publicly available information through an intelligence network would be beneficial for all participants, especially authorities in developing countries. The intelligence network may set up a system of alerts to inform competition authorities about cartels that have been successfully prosecuted, including techniques of detection and evidence gathering. Another idea is to establish an international data bank containing a list of all cartel members or businesses involved in serious and repetitive violations. Such schemes would ensure the continuity of international efforts to prosecute cartels and send a strong signal that cartels may be investigated and sanctioned in other jurisdictions.

52. With regard to mergers, the importance of cooperation in regulating cross-border mergers has been stressed by both developed and developing countries. The worldwide proliferation of merger control regimes has the advantage of improved monitoring of merger activities. However, without cooperation and coordination between competition agencies, there are significant drawbacks to this development, from a business perspective (additional complexity, legal uncertainty and differences in timing and costs) and from a competition authority perspective (inconsistent or conflicting decisions). Convergence between merger control regimes has therefore been encouraged by the International Competition Network (see for example the Recommended Practices for Merger Notification Procedures, available at http://www.internationalcompetitionnetwork.org/uploads/library/doc588.pdf).

53. Cooperation in cross-border mergers may occur at multilateral, regional and bilateral levels and may be facilitated by competition provisions in regional or bilateral arrangements or be done on an informal case-by-case basis. Some countries have stressed the need for cooperation in cross-border mergers, particularly with respect to the assessment of appropriate remedies, and stated that they have found informal cooperation more useful in the selection and design of remedies than formal agreements and memorandums of understanding.[8] Informal cooperation may provide opportunities for exchanging experiences on methodologies and tools for estimating the effects of and potential risks that may arise from a merger and seeking advice on remedies that have been successfully implemented in similar cases in other countries and those which should be avoided.

54. Combining enforcement efforts at the regional level is another strategy to deal with the cross-border effects of anticompetitive practices in a region. This may facilitate more efficient and effective enforcement against such anticompetitive behaviour. An innovation in this direction is the Lima Declaration, signed by the heads of the three competition authorities of Colombia, Chile and Peru and UNCTAD in 2013. This instrument for informal cooperation aims to create a platform for exchanging experiences and training

[6] TD/B/C.I/CLP/10.
[7] TD/B/C.I/CLP/16.
[8] Ibid.

among the three agencies and conducting studies on topics of common interest. This cooperation framework has been used in a common investigation and regular trilateral and bilateral meetings have been held among the agencies.

55. Encouraging progress has been made in other regional groupings. Member States of the Association of South-East Asian Nations have committed to introducing national competition policy and law by 2015. The Competition Commission of the Common Market for Eastern and Southern Africa became operational in 2013 and began reviewing mergers affecting multiple jurisdictions in the region. The Southern African Development Community commits its member States to pursuing case-specific cooperation to the extent consistent with each member's laws, regulations and important common interests in preventing hard-core cartels, abuse of dominance, anticompetitive mergers and unilateral conduct and, for this purpose, launched an online data bank in 2012 to exchange non-confidential information on ongoing and closed competition cases.

56. The success of the European Competition Network suggests possible useful elements for other regional groups. More importantly, it highlights how the harmonization of substantive rules is necessary, but not sufficient, to reduce regulatory burdens and uncertainty. Procedural rules and domestic legal structures also play an important role.

57. UNCTAD, through its voluntary peer review process, has contributed to informal cooperation efforts among competition agencies, including cross pollination between young and mature competition agencies. One appreciated and innovative feature of voluntary peer reviews is the review of regional competition arrangements, such as those of the West African Economic and Monetary Union and its member States and the tripartite review for the United Republic of Tanzania, Zambia and Zimbabwe. The two reports and their respective recommendations highlighted appropriate areas where inter-agency cooperation may be the most useful and proposed reforms and the adoption of best practices.[9]

58. Two other cooperation initiatives launched by UNCTAD are the UNCTAD and Latin American and Caribbean Economic System Working Group on Trade and Competition established in 2008 and, most recently, the UNCTAD Collaborative Information Platform, launched in July 2013.[10] The working group is comprised of trade and competition experts from 25 countries in Latin America and the Caribbean. It focuses on the exchange of information, experiences and best practices in order to enhance cooperation efforts in dealing with trade and competition issues. The platform is an online database for competition cases, which allows competition agencies to post and access information on cases handled by other agencies. National competition authorities may then use this information to handle similar cases in their jurisdictions. In this way, the platform may facilitate collaboration in ongoing investigations.[11]

59. Nonetheless, there is still work to be done in order for young competition agencies or those of small or developing economies to benefit from cooperation. Many of these agencies are not party to effective formal bilateral or regional agreements. Most bilateral agreements are between developed countries. One reason for this is that developed countries focus on economies whose commercial activities are likely to impact their markets. Businesses from smaller economies are less likely to have such international reach. Limitations to cooperation also arise from differences in competition laws, procedures, legal regimes and efficiencies of court systems, as well as from insufficient mutual trust and understanding. Resource and capacity constraints faced by competition

[9] TD/B/C.I/CLP/21.

[10] A Ezrachi and H Qaqaya, 2012, UNCTAD's Collaborative Information Platform, *Concurrences Competition Law Journal*, 4:204-207.

[11] TD/B/C.I/CLP/29.

authorities in developing countries are another factor in restricting cooperation possibilities with their counterparts, especially in developed countries. The benefits to more advanced jurisdictions of entering into bilateral agreements with their counterparts in developing countries may not be immediate, but in the long term, the harmonization of competition law and policy that may result from repeated interactions may benefit both jurisdictions.

60. Recent cooperation agreements between advanced and emerging economies indicate that cooperation is an evolutionary process, which involves the gradual adaptation of rules and procedures and mutual trust. Informal cooperation through capacity-building and exchanges of knowledge and experiences can play an important role in upgrading skills and closing the gap between competition agencies. It is this gap in technical capacity, legal regimes and mutual trust that requires attention if cooperation in the area of competition policy is to be enhanced and expanded.

61. UNCTAD studies suggest the following steps for moving forward in international cooperation:[12]

(a) Promoting better understanding of each other's laws, assessment criteria and designs of remedies and sanctions;

(b) Building the human and technical capacities of young competition agencies to enforce competition law;

(c) Developing guidelines and best practices for cooperation agreements based on what works well and what does not work;

(d) Exchanging staff and detaching resident advisors to promote mutual understanding and trust;

(e) Promoting transparency in procedures, processes and design;

(f) Assuring the inclusion of provisions in national laws allowing for cooperation and for exchanges of information for enforcement purposes;

(g) Establishing and implementing clear safeguards for due process and the protection of confidential information.

62. The existing regional frameworks could be used to promote and facilitate international cooperation in competition law enforcement. This is in line with the Set, which provides for the establishment of appropriate mechanisms at regional and subregional levels to promote exchanges of information on anticompetitive practices and on the application of national laws and policies in this area, as well as to provide mutual assistance in anticompetitive practices control (article E.7). It is also in line with the Accra Accord, which provides that UNCTAD should continue analytical work and capacity-building activities to assist developing countries on issues related to competition law and policy, including at a regional level (paragraph 104). In this context, UNCTAD is increasingly engaged in capacity-building activities not only at national but also at the subregional and regional levels. A report to the Seventh Review Conference lists capacity-building efforts by UNCTAD in the last five years.[13]

[12] Ibid and TD/B/C.I/CLP/21.

[13] TD/RBP/CONF.8/7.

III. Outlook for the Seventh Review Conference

63. On the basis of the above developments, the Seventh Review Conference may wish to reflect on possible topics in the area of competition and consumer policies that UNCTAD should focus on in the next five years, taking into account the guidance set out in paragraphs 8 and 11 of the resolution adopted by the Sixth Review Conference, and items covered in the meetings of the Intergovernmental Group of Experts on Competition Law and Policy held in the period under review.

64. Member States may wish to determine the specific topics to be covered in the period leading to the Eighth Review Conference in 2020, in light of how such topics fit under the following broad categories: appropriate design and enforcement of competition law and policy; international cooperation and networking; cost-effectiveness, complementarity and collaboration in the provision of capacity-building and technical assistance to interested countries; consultations on and revision of the model law; issues related to cases concerning anticompetitive practices and other issues relevant to competition that have been raised by member States; and issues in the extension of competition and consumer policy to new areas such as emerging markets for social services traditionally provided by Governments and the appropriate design and institutional framework for their application. It would also be appropriate to take into account current trends and issues in both competition policy and international trade and development trends.

65. Taking into account the above, member States may wish to consider the following in determining possible topics to be covered by meetings of the Intergovernmental Group of Experts on Competition Law and Policy over the next five years:

(a) Considering the broader development context, that is, the United Nations summit for adoption of the post-2015 development agenda, to be held in September 2015, it would be relevant for UNCTAD to look into the role of competition law and policy in achieving sustainable and inclusive growth and, specifically, the role of competition policy with respect to attainment of sustainable development goals (for the proposal currently under consideration, see https://sustainabledevelopment.un.org/focussdgs.html).

(b) Recognizing the increasing trend towards inclusion of competition policy provisions in regional trade agreements and implications of cross-border anticompetitive practices for intraregional and international trade, it would be useful to look into ways in which national competition and regulatory policies could help implement such provisions and foster competition at regional and international levels.

(c) Recognizing the role of effective competition agencies in dealing with anticompetitive practices, it would be important to re-emphasize the work of UNCTAD on appropriate institutional structures and working methods to improve agency effectiveness in competition law enforcement while adhering to procedural fairness.

(d) Considering the increasingly cross-border nature of anticompetitive practices due to globalization, continued support by UNCTAD for appropriate competition law enforcement by national competition authorities and cooperation between them in such enforcement remains crucial in dealing with anticompetitive practices of this nature.

(e) Many developing countries have adopted competition and consumer laws and set up relevant institutions in the past decade. Recognizing the increased number of young competition and consumer protection agencies, the work of UNCTAD on technical assistance and capacity-building in the area of competition and consumer protection continues to be relevant and crucial for developing and least developed countries and countries with economies in transition.

(f) Considering the success of the Ad Hoc Expert Group Meetings on issues related to the interface between competition and consumer protection, competition and sustainable development and revision of the United Nations Guidelines on Consumer Protection, as well as the interest shown in ensuing consultations for the creation of an Intergovernmental Group of Experts on Consumer Protection Law and Policy in UNCTAD, and therefore establishing yearly Ad Hoc Expert Group Meetings on consumer protection until the eventual establishment of such a body.

(g) Acknowledging research and policy analysis as a main pillar through which UNCTAD supports member States and the growth of the UNCTAD Research Partnership Platform since the last Review Conference, and therefore providing support for the platform to expand its activities towards stakeholder conferences and seminars and training courses and workshops in developing countries, in light of the issues faced by these countries and ongoing work by UNCTAD on competition policy.

(h) Recognizing the need for increased cooperation between international bodies and networks that address competition law and policy and interfacing issues remains important.

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Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices

Geneva, 6–10 July 2015

Item 6 (b) of the provisional agenda

Consideration of proposals for the improvement and further development of the Set, including international cooperation in the field of control of restrictive business practices

The role of competition in the pharmaceutical sector and its benefits for consumers

Note by the UNCTAD secretariat

Executive summary

Competition policy aims to make markets work for consumers through its core elements: enforcement and advocacy. Nevertheless, when pursuing better access to products, measures against anticompetitive behaviour in the pharmaceutical sector may not be the best starting point, in comparison with other areas of law. As a relatively underdeveloped yet promising mechanism for doing so, competition policy should be given greater prominence for its potential to complement efforts in this area. This report addresses some of the main competition problems in the pharmaceutical industry today. It gives examples from various jurisdictions on the benefits of competition enforcement for consumers and recommends some measures to enhance competition advocacy in the pharmaceutical industry.

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Introduction

1. The pharmaceutical industry plays an important role in improving global health care. Three of the eight Millennium Development Goals call for specific health care improvements by 2015. However, around two billion people worldwide have inadequate access to essential medicines and vaccines, or none at all.

2. Disease and poverty are interdependent. People are often sick because they are poor. They may become poorer because they are sick and sicker because they are poorer. Yet, many of the illnesses affecting people living in poverty can be prevented, alleviated or cured with a relatively small number of essential medicines if they are available at affordable prices.

3. Limited public health services budgets and steadily increasing expenses slow economic growth.[1] Meanwhile, drug expenditures keep rising. In 2011, the total pharmaceutical bill across countries of the Organization of Economic Cooperation and Development (OECD) was about $800 billion. In 2013, global pharmaceutical sales reached an all-time high of approximately $980 billion and are expected to rise beyond one trillion dollars by 2015.[2]

4. Competition is important because it compels industry to provide higher quality goods and services at lower prices. In the pharmaceutical industry, competition can motivate brand companies to create new and improved medicines and encourage generic companies to offer less expensive alternatives.

5. On average, pharmaceutical spending accounted for 1.5 per cent of gross domestic product (GDP), with about 0.8 per cent of GDP publicly financed, and the remainder, from private sources.[3] Competition policy can improve both consumer and government access to affordable pharmaceuticals through two core elements: enforcement and advocacy.

6. Throughout much of the world, however, administrative regulation, rather than competition policy, dominates efforts to afford consumers and governments adequate access to affordable drugs.

7. Although strict administrative regulation has stabilized prices for certain drugs, it has also deepened competition enforcement challenges in the private sector. Also, competition advocacy contributes towards a more transparent, efficient and consumer-friendly administrative regulation environment. Competition policy is important in both the public and private sectors and should be given greater prominence to complement other efforts in this area.

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[1] Federal Antimonopoly Service of Russia [the Russian Federation], 2013, Results of the Assessment of Pharmaceuticals Affordability on Basis of the Analysis of Consumer Prices and Price Setting for Pharmaceuticals in the Russian Federation (Federal subjects included) and on Comparable Markets of other Countries, Comprising the CIS [Commonwealth of Independent States], European Union and BRICS [Brazil, the Russian Federation, India, China and South Africa]. Available at http://en.fas.gov.ru/netcat_files/560/719/h_16877705280114952718 36c96cbf82ec. accessed 29 September 2014.

[2] Thomson Reuters, 2014, Thomson Reuters Annual Pharmaceutical Factbook projects industry's sales will reach $1 trillion in 2014, available at http://thomsonreuters.com/en/press-releases/2014/thomson-reuters-annual-pharmaceutical-factbook-projects-industrys-sales-will-reach-1-trillion-in-2014.html, accessed 27 April 2015.

[3] OECD, 2013, *Health at a Glance 2013: OECD Indicators*, OECD Publishing, available at http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf, accessed 28 October 2014.

8. This report addresses some competition problems in the pharmaceutical industry, gives examples from various jurisdictions on how competition enforcement benefits consumers and recommends measures to enhance competition advocacy in the pharmaceutical industry.

9. This report draws from recent research and international reports in this area, such as reports by UNCTAD, the United Nations Office for Project Services, the World Intellectual Property Organization, the World Health Organization (WHO), OECD and the European Union.

I. Competition problems

10. In general, the low elasticity of demand associated with in the pharmaceutical industry can be attributed to the must-have nature of many drugs, owing to the lack of alternatives and regulatory requirements on the range of the products that providers must offer and insurers must cover. The supply of brand drugs is characterized by considerable market power because of the presence of patents to reward the high investment in research and development that brand drug companies maintain is necessary to bring new drugs to market. Notwithstanding the rise of generic companies in emerging countries leading to more robust competition, there has been no significant change in the ranking of the leading pharmaceutical companies. This creates competition concerns, and prices continue to rise owing to these market features.

Table 1
Top 10 pharmaceutical companies by revenue

	2013	*2012*	*2011*	*2010*
1	Pfizer (United States of America)	Pfizer	Pfizer	Pfizer
2	Novartis (Switzerland)	Novartis	Novartis	Novartis
3	Roche (Switzerland)	Merck and Co.	Merck and Co.	Sanofi
4	Merck and Co. (United States)	Sanofi	Sanofi	Merck and Co.
5	Sanofi (France)	Roche	Roche	GlaxoSmithKline
6	GlaxoSmithKline (United Kingdom of Great Britain and Northern Ireland)	GlaxoSmithKline	GlaxoSmithKline	Roche
7	Johnson and Johnson (United States)	AstraZeneca	AstraZeneca	AstraZeneca
8	AstraZeneca (United Kingdom)	Johnson and Johnson	Johnson and Johnson	Johnson and Johnson
9	Lilly (United States)	Lilly	Lilly	Lilly
10	AbbVie (United States)	Teva	Teva	AbbVie

Source: PM Group, 2015, Top 25 pharma companies by global sales. PM Live, available at http://www.pmlive.com/top_pharma_list/global_revenues, accessed 1 November 2014.

A. Competition concerns in the public sector

11. Countries take measures to regulate prices in order to streamline expenses for pharmaceuticals and reduce drug prices in the public health care systems. Pharmaceutical

pricing practices and controls vary across countries. Where the products in a therapeutic class are close substitutes, the prices of the drugs in that class are often set equal to the lowest price in that class. Where a drug has few close substitutes, it is also common to set prices based on international price comparisons of equivalent drugs. Where a drug is covered by the list of vital and essential drugs,[4] procedures for the establishment of wholesale and retail trade markups and their maximum rate are strictly regulated. Some countries also regulate the prices and services of pharmaceutical wholesalers to keep a check on possible market manipulations. However, administrative regulation also can create competition concerns.

12. First, rigid price regulation has stabilized the prices of certain drugs, but reduced the availability of inexpensive alternatives to brand name drugs and increased the markups on unregulated medicines, as the wholesalers and retailers have shifted their lost profit to expensive unregulated drugs. For example, analyst agencies data for 2011 indicate that the average prices of drugs used for medical purposes rose by 8.8 per cent, in contrast to 10.8 per cent for drugs not covered by the model list of essential medicines, and a decrease of 3.3 per cent, for those drugs listed for medical use.[5]

13. Second, governments are notoriously inefficient buyers.[6] In some countries, government representatives entrusted with power to determine prices in negotiation with monopoly manufacturers might abuse that power for private gain, wasting public resources. A lack of accountability and transparency during tender and negotiation can provide a breeding ground for corruption, creating competition concerns. Corruption in public procurement could create an uneven playing field that affects competition.

14. Third, in some public health distribution systems, physicians influence drug sales, and patients are misled into purchasing more expensive medicines. Since only physicians have the right to issue prescriptions, while patients have no choice in medication, the practices of bribe and rebate – not price and quality – may determine which drugs are chosen. In some countries, corruption-related anticompetitive practices directly increase the price of medicines and restrict consumers' access to effective and affordable medicine. In India, for example, given the anticompetitive practices common to the health delivery system, only 35 per cent per cent of Indians have access to essential medicines.[7] Stakeholders in Tajikistan and Costa Rica contend that the lack of transparency contributes to the siphoning of public resources into a physician's private hospital or practices.[8]

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[4] Essential drugs, as defined by WHO, are "those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford" (resolution WHA31.32). They are contained in the WHO Model List of Essential Medecines (eighteenth edition) of April 2013.

[5] See note 1.

[6] J Clark, 2005, Competition advocacy: Challenges for developing countries, *OECD Journal of Competition Law and Policy*, 6(4): 69–80, available at http://www.oecd-ilibrary.org/docserver/download/2404051ec003.pdf?expires=1429540476&id=id&accname=ocid57015274&checksum=F35EC94A2EDDF8D196B24D62017BF391, accessed 24 April 2015.

[7] CUTS Center for Competition, Investment and Economic Regulation, 2008, Dealing with anticompetitive practices in the Indian pharmaceuticals and the health delivery sector, Briefing Paper No. 5, available at http://www.cuts-international.org/pdf/CCIER-3-2008.pdf, accessed 20 April 2015.

[8] United Nations Development Programme, 2014, Building transparency, accountability and anti-corruption into the post-2015 development framework, Discussion Paper, available at http://workspace.unpan.org/sites/Internet/Documents/UNPAN93602.pdf, accessed 20 April 2015.

B. Competition concerns in the private sector

15. In the private sector, supply- and demand-side anticompetitive practices are prevalent.

16. On the supply side, typical horizontal agreements such as bid rigging, cartels and boycotts, are conventional tools that are used to fix prices and earn monopoly profits. Pay-for-delay agreements, a less conventional yet prevalent anticompetitive practice, deserve close attention from competition authorities. These agreements are common when a patent holder settles patent litigation by paying a generic pharmaceutical competitor to delay or abandon its plan to launch a competing drug. In 2010, the United States Federal Trade Commission estimated that pay-for-delay settlements cost American consumers $3.5 billion annually. As a result, United States competition agencies have repeatedly attacked this type of agreement in court, participated as amici in private actions and supported legislative efforts to curb such agreements.[9]

17. Regarding unilateral conduct by drug makers, patent owners' abuse of dominance raises major barriers to market entry for generic products. New drug developers argue that the research, development and marketing of new pharmaceutical products is very expensive and risky. Originator producers usually seek patent protection for their products, and variations thereof, for as long as possible and therefore have an incentive to restrict competition.

18. For many years, a brand company's main strategy for blocking or delaying generic companies was to refuse licensing or to charge unreasonably high royalties. For example, setting an unreasonable high royalty may be considered an implicit refusal to license. Competition-based licences authorize a person to exploit patents in order to market generic versions of patented medicines or dose combinations in return for payment of a reasonable royalty.[10] If access to medicines that are used to treat chronic illnesses or that constitute life-saving therapy is unreasonably restricted, particularly for illnesses affecting people living in poverty, some Governments will issue general public interest licences.

19. In recent years, originator companies have developed more sophisticated anticompetitive strategies to block or delay the development or market access of generic products, mainly by engaging in evergreening, product hopping and sham litigation.

20. Evergreening strategies help originator companies obtain the most efficient, broadest and longest possible patent protection for their products and variations. To ensure exclusivity, at least until the end of the base patent protection period, originator companies may file many patent applications on process, formulation and dosage regimes, which can be broad in both scope and claim. This is often referred to as a patent cluster. A divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides a parent patent application into one or more narrower patent applications.[11]

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[9] OECD, 2014, Summary record of the Discussion on competition and generic pharmaceuticals, DAF/COMP/M (2014)2/ANN3, 6 November, available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M%282014%292/ANN3/FINAL&doclanguage=en, accessed 24 April 2015.

[10] SM Flynn, 2014, Using Competition Law to Promote Access to Medicines, https://www.wcl.american.edu/pijip/download.cfm?downloadfile=34080B0A-C32A-6A22-22ED8491FC3EB62B, accessed 27 April 2015.

[11] European Commission, 2008, Executive Summary of the Pharmaceutical Sector Inquiry Report, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf, accessed 20 April 2015.

21. The denser the patent cluster or divisional patent, the more difficult it will be for a generic company to bring its generic version of the original pharmaceutical product to the market. All generic manufacturers know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that their product will not infringe and thus become the subject of an interim injunction. That is to say, although the main patent protecting the product, for example the basic substance patent, may have expired, the generic version may still infringe one of the multiple patents surrounding the original pharmaceutical. This kind of patent application strategy serves to secure an optimal competitive position for originator companies' products in the market by creating significant legal and commercial uncertainty of viable generic entry to block competitors. Therefore, patent clusters and divisional patents seem to be aimed at creating legal uncertainty for generic competitors; nevertheless, they may signify an increase of incremental innovation. As for the enforcement efforts against this type of patent strategy, the decision of Italy's highest administrative court in the Pfizer case, outlined below, represents the most current development on this topic.

22. In some cases, patent clusters and divisional patents might be used as indispensable assets for originator companies to engage in patent litigation, which will create obstacles to market entry of generics, namely by creating costs and using injunctions preventing the sale of the generic product. While larger generic companies may have the financial resources to undertake long and costly litigation, smaller companies may be more substantially affected by increasing litigation costs. Interim injunctions prevent a small generic company from selling its product, whereas the originator company will continue to collect revenues from its product in the name of zero tolerance to any patent infringements.

23. Product hopping or product switching generally involves branded manufacturers introducing new formulations of patented drugs shortly before the patent protection on the older version of the drug expires, and then withdrawing the older drug that faces imminent generic competition. This conduct often allegedly involves the steering of physicians or pharmacists to "hop" demand over to the new branded drug formulation, which is protected by a long-term patent. As generic drugs tend to rely on substitution rules that allow pharmacies to swap the generic equivalent for a branded drug, when physicians stop writing prescriptions for the older drug, this eliminates the possibility of substitution and thus the possibility of meaningful generic competition.[12]

24. Mergers and acquisitions have been widespread in recent years. In the first half of 2014, the top 10 transactions totalled nearly $90 billion.[13] Historically, investment in research and development to generate a flow of new chemical entities has been the business model for pharmaceutical transnational corporations with headquarters in developed countries. However, several changes have taken place. First, many companies are facing soon-to-expire patents, comprising up to 70 per cent of some companies' total sales. Second, Indian, Chinese and Brazilian generic companies are growing rapidly, leading to a highly global competitive environment.[14] These changes lead to the demise of the research and development investment model, and a wave of mergers and acquisitions where large research and development-based transnational corporations are buying generic companies with potential new drug pipelines, such as Roche and Genentech, Sanofi Aventis and Genzyme, and Daichi Sankyo and Ranbaxy. Most developing world generic markets are

[12] GN Addy and E Douglas, 2014, Canada considers hopping on board with a product-hopping case, *Competition Policy International, Antitrust Chronicle Competition Policy*, Spring 2014, Vol. 3, No. 2.

[13] FiercePharma, 2014, Pharma's top 10 M&A deals of 2014's first half, 28 October, available at http://www.fiercepharma.com/special-reports/pharmas-top-10-ma-deals-2014s-first-half, accessed 20 April 2015.

[14] UNCTAD-International Centre for Trade and Sustainable Development, 2011, The structural changes in the global pharmaceutical marketplace and their possible implications for intellectual property, Policy Brief No. 10, July.

called branded generic markets, as the medicines carry a local brand name instead of the scientific generic name.

25. On the demand side, a significant role assumed by physicians in influencing drug sales in some countries has resulted in patients being misled into purchasing more expensive medicines. Activities involving inappropriate payments to hospitals and doctors have concerned regulators for many years. The pharmaceuticals, through rebates, unduly turned consumer (patient) benefits into the medical institution's proceeds.

26. In distribution chains, vertical restraints in supply and sales agreements to prevent retailers and wholesalers from obtaining supply from competitors are also fairly widespread. The Fair Trade Commission of the Republic of Korea found that 55 per cent of pharmaceutical supply and sales contract terms prevented buyers from dealing with possible rival products and imposed sales quotas in that country. Some clauses on no-rival product requirements were structured to outlast the contract itself. To address unfairness and improve consumer welfare, the Fair Trade Commission codified new guidelines for fair pharmaceutical transactions, which do not allow the following:

(a) Restrictions on research and development and production, as well as prohibitions on dealing with rival products after contract termination;

(b) Automatic contract terminations upon failure to reach a minimum purchase or sales quota;

(c) Unconditional transfers of technological innovations developed fully by a buyer, and allowing only exclusive raw material purchase in exceptional cases for product quality control. Moreover, horizontal agreements at the distribution level are also possible, as shown by recent action taken by the Brazilian competition authority.[15]

II. Case examples: How competition enforcement benefits consumers

27. In the pharmaceutical industry, competition policy benefits consumers in the form of increased accessibility to medicines at affordable prices, both in the public sector and on the commercial market. Competition enforcement benefits consumers by detecting, halting, and correcting anticompetitive practices. Table 2 gives examples of price reductions achieved through the use of competition enforcement in the industry.

[15] OECD, 2014, Competition issues in the distribution of pharmaceuticals: Contribution from the United States, DAF/COMP/GF/WD (2014) 43, 10 February.

Table 2
Examples of competition legal action in the pharmaceutical industry

Country and date of action	*Description of action*	*Pharmaceutical products*	*Impact*
France, 2013	Following complaint by Teva, French competition authority found Sanofi-Aventis had abused a dominant position with a strategy to denigrate generic versions of its branded drug, Plavix	Clopidogrel	Sanofi-Aventis fined €40.6 million.
European Union, 2012	European Court of Justice affirmed Commission findings of abuse of dominant position by AstraZeneca in providing misleading information to patent offices and deregistering product to inhibit generic entry	Losec	AstraZeneca fined €52.5 million
Colombia, 2009	Finding fewer than three homogenous products on the market, National Medicines Pricing Commission regulated price of medicine sold by Abbott Laboratories	Lopinavir and Ritonavir	Average price reduction ranging between 54 per cent and 68 per cent per person per year
Italy, 2007	Competition authority initiated investigation into abuse of dominant position by Merck	API Finastertide	Defendant agreed to grant free licences to allow manufacture and sale of API prior to expiration of patent term
South Africa, 2003	Competition Commission found two pharmaceutical companies guilty of excessive pricing and denying a competitor an essential facility, following complaints from activist groups	AZT, lamivudine and nevirapine and fixed-dose combinations containing these anti-retrovirals.	Led to voluntary settlement agreements with GlaxoSmithKline and Boehringerlngelheim providing licensing of patents to seven generic companies, based on 5 per cent royalties
United States, 2000	Federal Trade Commission charged generic producers with restraint of trade and conspiracy to monopolize markets for two generic drugs; settlement agreed	Lorazepam and Clorazepate	Lead defendant (Mylan) placed $100 million into escrow account for distribution to purchasers of relevant drugs during time period covered by settlement

Source: United Nations Development Programme, 2014, *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, New York.

A. Competition enforcement against horizontal agreements

28. Measures employed against bid rigging in public procurement processes are a key tool of competition enforcement, especially in developing countries where government spending accounts for a higher percentage of GDP.

29. In May 2006, the Competition Commission of Mexico requested information from the Mexican Institute of Social Security (IMSS), the biggest health services provider in Latin America, regarding its bidding procedures for acquiring medicines. The material provided evinced the presence of collusion in the IMSS public procurement process. The investigation focused on public bidding from 2003 to 2006 for two specific products, human insulin and electrolytic solutions, and demonstrated constant communication between participating firms, particularly across the dates nearing the bids. Consequently, the Commission in 2010 fined six pharmaceutical companies 151.7 million pesos, a decision that was supported by the Mexican judiciary. Increased competition benefited consumers by average price falls: 68.1 per cent for human insulin and 12.1 per cent for electrolytic solutions.[16]

30. Another example of enforcement against horizontal anticompetitive agreements can be found in a Spanish boycott case. In 2007, Laboratorios DAVUR (DAVUR) filed a complaint against four pharmacy associations, claiming a collective boycott. DAVUR decided to lower the price of 12 of its generic pharmaceuticals to below the reference prices set by the Health Ministry. Subsequently, several pharmacy associations made recommendations to almost all pharmacies in Spain to stop stocking DAVUR medicines. These associations noted that, since DAVUR's lower prices could reduce the reference prices of generic medicines as set by the Health Ministry and thus decrease the associations' future revenues, those associations recommended the restriction of DAVUR's products. As a result, many Spanish pharmacists stopped dealing with DAVUR and impeded the entry of its products. During the investigation, DAVUR settled with the main claimants and withdrew its complaint. Nevertheless, the investigation continued ex officio. In March 2009, the Spanish competition authority resolved to declare the existence of an infringement and imposed a total fine of €1 million on the associations.[17]

31. The Actavis case in the United States and the Lundbeck case in the European Union represent the most recent enforcement trends in unconventional pay-for-delay agreements.

Box 1. Pay-for-delay cases in the United States and the European Union

In the *Federal Trade Commission v. Actavis*, Actavis, then Watson Pharmaceuticals, filed an abbreviated new drug application, seeking approval to market a generic drug modelled on a patented synthetic testosterone, AndroGel. The owner of the patent, Solvay Pharmaceuticals, filed suit against Actavis and others for patent infringement. In 2006, the parties entered into a settlement whereby Solvay (the patent owner) agreed to pay Actavis (the alleged infringer) $19 million to $30 million a year for nine years. Additionally, Actavis agreed to delay entry into the market until 31 August 2015, about five years before expiration of the patent. On 17 June 2013, the the United States Supreme Court held that the rule of reason would apply to reverse payment settlements.

Following the Actavis case, the European Commission fined the Danish pharmaceutical company Lundbeck €93.8 million for entering into reverse payment settlements with several generic producers (Alpharma, Arrow, Merck KGaA/Generics (United Kingdom) and Ranbaxy), which were also fined between €9.9 million and €21.4 million each. This was the first time the Commission had fined companies on the grounds that reverse payment settlements contravened European Union competition law.

[16] Contribution from Mexico to the UNCTAD round table on the benefits of competition policy for consumers, Intergovernmental Group of Experts on Competition Law and Policy, fourteenth session, Geneva, 8–10 July 2014.

[17] OECD, 2014, Competition issues in the distribution of pharmaceuticals: Contribution from Spain, DAF/COMP/GF/WD (2014) 47, 10 February.

In the Lundbeck case, the manufacturer of Citalopram, a "blockbuster" antidepressant medicine, held patents covering both the citalopram molecule and the process by which the molecule is manufactured. As the 2003 patent expiry date for the citalopram molecule approached, Lundbeck brought patent disputes against generic companies proposing to enter the market with generic versions of citalopram, for infringing its manufacturing process patent. The parties ultimately settled the disputes on terms that included significant payments by Lundbeck to generic companies. The Commission observed that once generic citalopram did enter the British market, prices dropped by 90 per cent on average. This reinforced its view that Lundbeck and the relevant generics were sharing monopoly rents among themselves.

Source: Ashurst Australia, 2013, EU [European Union] Commission issues first fines for "reverse payment" settlements, 25 June, available at www.ashurst.com/page.aspx?id_content=9268, accessed 21 April 2015.

32. In addition to agreements between suppliers, horizontal agreements at the retail level are also possible. In January 2014, the Administrative Council for Economic Defence of Brazil (CADE) ruled against a drugstore cartel in Curitibanos, a city located in Santa Catarina state, and imposed sanctions on all participating companies. The administrative process was started because a representation was sent to CADE by the Office of the Public Prosecutor. The alleged conduct consisted of agreements between drugstores to establish specific days of the week when each competitor would offer discounts. Therefore, CADE concluded that drugstores illegally colluded to establish a rational system of discounts and imposed fines amounting to R$1.5 million.[18]

B. Competition enforcement against vertical agreements

33. In distribution chains, vertical restraints in supply and sales agreements to prevent retailers and wholesalers from obtaining supply from competitors are also fairly common.

34. In France, Schering-Plough's patent for Subutex had expired. Three months before market entry by its generic competitor, Schering-Plough began offering large discounts, similar to loyalty discounts, to pharmacists on the sale of Subutex. The only purpose of these discounts was to prevent pharmacies from obtaining supply from the generic manufacturer. According to regulations in France, generic firms are allowed to offer much larger discounts (10.74 per cent) than originator firms (2.5 per cent). To bypass this regulation, Schering-Plough paid pharmacists for alleged services. The French competition authority determined, however, that the volume of granted discounts did not depend on the service pharmacists provided, but on the quantity of the purchased drugs. As a result, pharmacists obtained such a massive supply of Subutex that there was no room left for the generic version when it entered the market. In December 2013, the competition authority ruled that Schering-Plough had abused its dominant position through its discount strategy and imposed a €15.3 million fine on the company.[19]

35. In China, the National Development and Reform Commission found that two pharmaceutical companies, Shuntong and Huaxin, had signed exclusive distribution agreements with the only two domestic producers, allowing them to control the supply of promethazine hydrochloride, a key raw material for the compound reserpine, commonly used in high blood pressure treatments. These agreements required the producers to obtain

[18] Administrative Process No. 08012.004365/2010-66.

[19] See note 9.

approval from both companies before selling the product to any other party, in order to eliminate competition. In 2011, the Commission fined the companies RMB 7 million.[20]

C. Competition enforcement against unilateral conduct

36. Regarding refusal to license, a strategy employed for blocking entry of generic companies, several complaints were filed from 2002 to 2007 with the South African Competition Commission alleging the abuse by multinational pharmaceutical companies of intellectual property rights concerning drugs used to treat HIV/AIDS. These major branded pharmaceutical firms had failed to license their patents on reasonable terms to generic firms in a country where the targeted disease was a serious public health-care issue. Since the firms were willing to settle the case during the investigation, there was no need for a competition enforcement decision. Under the settlement, both companies agreed as follows:

(a) To grant licences to the generic firms;

(b) To permit the licensed firms to sell generic products in the region;

(c) To permit the licensed generic firms to mix the drugs so as to create better combinations for patients;

(d) Not to require royalties above 5 per cent of their net sales.

37. This settlement enabled generic competition and led to lower prices to the benefit of patients. A 2006 study showed that the price of one of the branded drugs to treat HIV/AIDS fell by more than 50 per cent between 2002 and 2006, while the generic equivalent was even cheaper.[21]

38. A recent decision on evergreening by an Italian court was key in developing the legal rule concerning the abuse of intellectual property rights, striking a balance between the rights of inventors and consumers through competition enforcement (see box 2).

39. An example of product hopping or product switching can be found in a recent case in the United Kingdom. Reckitt Benckiser, the multinational consumer goods company, marketed a drug called Gaviscon Original. After the patent expired but before a generic was introduced, Reckitt Benckiser launched a new version of the drug called Gaviscon Advanced. The company withdrew Gaviscon Original from the market and took measures to delay the introduction of a generic name.

40. In the United Kingdom, when the patent for a branded drug expires, the authorities introduce a generic name that doctors can apply to any generic equivalent of that drug. If the generic name is used on a prescription, the pharmacist is free to provide any appropriate drug, presumably the cheapest one. However, once a doctor prescribes a drug with a brand name, the pharmacist has to provide that drug, which cannot be substituted for a generic alternative. Reckitt Benckiser's strategy was set out in an internal e-mail, stating that "we should remind ourselves what our objective is here. To delay for as long as possible the introduction of a generic name and subsequent blacklisting of Gaviscon, while they cannibalize our existing franchise with Gaviscon Advanced". This is a fairly straightforward case, in which Reckitt Benckiser admitted liability early on and paid a fine.[22]

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[20] National Development and Reform Commission of China, 2011, available in Chinese only at http://xwzx.ndrc.gov.cn/mtfy/dfmt/201112/t20111207_449580.html, accessed 20 April 2015.

[21] See note 9.

[22] Ibid.

Box 2. Italy: The Administrative Supreme Court confirms the Italian competition authority's decision against evergreening

In 2012, the Italian competition authority sanctioned the multinational pharmaceutical group Pfizer, imposing a fine of €10,677,706. Pfizer's complex strategy consisted of several types of conduct, all proved and reasonably considered punishable by the competition authority. They included the following:

- The filing of divisional patent applications and the subsequent request of a Supplementary Protection Certificate, in order to extend the Italian patent protection many years after filing the main patent application, which still contained claims related to Latanoprost, and for which there was an absence of a commercial exploitation of a new product;
- Patent-related Court litigations hindering market entry of generic companies (shame litigation); (c) actions aimed at preventing the Italian Medicines Agency from granting geneticists marketing authorizations; and (d) application for a further patent protection extension through paediatric experimentation. All of these complex conducts, although individually and abstractly legitimate, could correctly be defined as abuse of rights and specifically anticompetitive. Pfizer refused to accept the penalty and brought administrative litigation to the Regional Administrative Court of Lazio, where the decision of the Competition Authority was annulled, as the Court held that Pfizer only tried to protect its legitimate interests, through types of conduct deemed lawful under patent law.

Following the Court's decision, the Competition Authority lodged an appeal before the Council of State, the highest administrative court on competition, against the decision of the Regional Administrative Court. The judge finished the reasoning of abuse by holding that such abuse of a dominant position belongs to the broader category of abuse of right. The doctrine of the abuse of rights includes the existence of a right; the possibility to effectively use such a right in different manners; the exercise of the right in a reprehensible manner, although formally legitimate; and the resulting unjustifiable disproportion between the benefit of the right's owner and the harm caused to the counterparty.

In other words, the abuse of rights does not suppose a formal infringement of laws, but the distorted exercise of the granted rights for purposes different from those intended by the legislator. Therefore, besides the legitimate nature of the right, the purpose to grant such legal right by the legislator shall be taken into account with more proportion when weighing the pros and cons in making a decision on the abuse of intellectual property rights. If the existence and exercise of industrial property rights are not of themselves incompatible with competition law, they are not immune from the application of competition law.

Source: C D'Amore, 2014, The administrative supreme court confirms the ICA's [Italian Competition Authority's] decision to condemn Pfizer for abuse of dominant position aimed at delaying the market entry of generic pharmaceutical companies, *Italian Antitrust Review*, 1:77–81.

D. Merger review

41. In the United States, some commentators have perceived tension between the Affordable Care Act and the antitrust laws in merger investigations since 2014. Partly due to the Act, which encourages provider integration, the health care sector has seen a significant consolidation. The Federal Trade Commission considers that the antitrust laws and the Act are compatible and that the goals of the latter are consistent with those of

competition policy. The Act seeks to promote higher quality care at lower cost through increased coordination and clinical integration. The Commission remains committed to its position that health care merger enforcement will continue to rely on traditional analytical approaches. In other words, it challenges the anticompetitive consolidation of hospitals or providers, but does not block collaborations where the evidence shows a transaction will result in lower costs, improved care and a net benefit to consumers.

42. In the pharmaceutical sector, merger enforcement has remained largely consistent in recent years. The Federal Trade Commission challenged the acquisition of Agila Specialties Global PteLtd and Agila Specialties Pvt Ltd. by Mylan, Inc. on 26 September 2013. It also adopted a final order in its challenge to the acquisition of Actavis, Inc. by Watson Pharmaceuticals on 14 December 2012. In both cases, the Commission required divestitures of various drugs to generic manufacturers based on its practice of defining relevant markets based on particular drugs, as opposed to courses of treatment for particular conditions. The Commission has been active in enforcement against 19 mergers in the branded and generic pharmaceutical sectors in the last five fiscal years.[23]

III. The role of competition policy

43. When competition policy acts beyond competition enforcement, it participates more broadly in the formulation of country's economic policies. In the pharmaceutical sector, competition advocacy acts proactively to lower entry barriers and promote competition. Through intervention in pre-grant and post-grant procedures relating to intellectual property, competition advocacy aims to strike a balance between the rights of inventors and consumers.

44. Another area in which competition policy can be especially helpful is public procurement, where procedures may invite collusion and corruption.[24] Successful advocacy in this area, along with working together with anti-corruption policies, will avoid the misuse of public funds and facilitate consumers' access to effective and affordable medication. Competition authorities may also help consumer empowerment through consumer education, facilitating consumer access to information and enhancing the capacity to correctly assess information to make optimal decisions. To conclude, competition policy is a crucial tool for building a transparent, anti-corruption, anti-monopoly and consumer-friendly environment. Coordination between competition authorities and other government agencies, such as consumer protection authorities and pharmaceutical sector regulators, will benefit consumers in the long term.

A. Striking a balance between the rights of inventors and consumers

45. Originator companies produce and sell pharmaceutical products developed during a research and development process deemed by drug companies to be lengthy and costly, and which involves substantial commercial risks. Brand drug companies contend that, on average, it takes 10–15 years to develop a medicine or vaccine. The research-based pharmaceutical industry maintains that it currently spends over $135 billion on research and development per year and that it costs an average of $1.38 billion to develop a single drug.[25] Brand drug companies argue that originator products are protected by intellectual property rights, in particular patent rights, because they give originator companies an

[23] See note 17.
[24] See note 6.
[25] Ibid.

opportunity to recoup investment costs and provide incentives for continued innovation.[26] This, the industry argues, makes important contributions to meeting patients' interests.[27]

46. In principle, generic companies produce and market an equivalent version of the original medicine once patent protection of that medicine has expired, inevitably resulting in a significant decline in price and market share of the original product. In the United States, the average price of generic drugs can be as much as 86 per cent less than that of their brand-name counterparts. In this context, competition concerns may arise when originator companies use their intellectual property rights to restrict or delay the market entry of generic medications.

47. The existence of a conflict between the rights of inventors and consumers depends on the balance between exclusiveness and public access.

48. Developed countries provide adequate protection to patent holders where domestic medicine manufacturing industries are competitive with proven invention capability, in order to maintain industry competitiveness in the global value chain.

49. In 2002, a decision by WTO members approved the delay of patent protection for least developed countries until 2021. Based on the weak invention capability of local drug makers, reverse engineering is allowed in order to encourage generic medication production.

50. For developing countries with pharmaceutical industries that have limited ability to make inventions, competition enforcement against generic pathway-related abuse is an important tool in promoting free access to health technologies. Therefore, where there is a conflict between competition and intellectual property policies, developing countries are inclined towards competition rather than exclusiveness. However, as the invention capability of domestic drug makers grows, a new balance will be needed.

51. Aside from the use of competition enforcement against abuse of dominance by originator companies, a toolbox has been designed for developing countries to shape the broad scope of exclusive rights before a patent is issued (pre-grant) and after a patent has been granted (post-grant), and thus ensure the accessibility of generic medications. This can be found in an UNCTAD reference guide for developing countries to use intellectual property rights to stimulate pharmaceutical production.[28]

52. Pre-grant flexibilities are a proactive tool that can be used by a Government to design and enforce intellectual property laws, such as employing a stricter standard of patentability criteria and patentable subject matter. In this context, competition advocacy is a useful tool for States to address competition concerns within existing patent systems and enact reforms not covered by the Agreement on Trade-Related Aspects of Intellectual Property Rights.

53. In 2014, South Africa began taking steps to achieve patent reform that would improve access to medicines and thereby strengthen the existing criteria for patentability. The current system allows pharmaceutical companies to obtain multiple patents on the same drug, even for inventions that do not fall under the country's definition of innovation. At present, the Competition and Consumer Policies branch of UNCTAD is assisting developing countries in striking a balance between intellectual property and competition

[26] See note 11.

[27] Ibid.

[28] UNCTAD, 2011, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide*, New York and Geneva, United Nations publication, available at http://unctad.org/en/pages/PublicationArchive.aspx?publicationid=437, accessed 20 April 2015.

policy by promoting the coordination between relevant authorities through joint capacity-building. This work started in October 2014 with projects with the Indonesian Government.

54. In Canada, the Competition Bureau may also intervene in Federal and Superior Court cases when it believes it is important to bring a competition perspective to proceedings that will not be brought by the parties. In other proceedings, when the Bureau believes that intellectual property rights could potentially be defined, strengthened or extended inappropriately, the Bureau may intervene to make representations concerning the scope of protection that should be accorded to intellectual property.

B. Cooperating with anti-corruption policies for good governance of public health resources

55. Given public health resource concerns, high levels of State-subsidized expenditures on pharmaceuticals provide sufficient motivation for all countries to make efforts to reduce drug prices. Centralized procurements and auction by tender are the most frequently used mechanisms. Successful advocacy in this area and cooperation with anti-corruption policies will avoid misuse of public funds and facilitate consumers' access to effective and affordable medication.

56. Collusion and corruption are distinct problems with public procurement; yet they may frequently occur in tandem and have mutually reinforcing effects. Collusion involves a horizontal relationship between public procurement bidders, and corruption occurs where public officials use public powers for personal gain.[29] Corruption is more prevalent in less competitive environments. By contrast, it is harder to offer bribes when many firms are competing in public procurement processes.[30] Well-designed procurement procedures can prevent collusion and corruption. In the European Union, all Member States must ensure that national measures to control prices of medicinal products or restrict the range of medicinal products covered by their national health insurance systems comply with the requirements of the Transparency Directive and the European Commission Treaty.

Box 3. Mexico: Cooperation between competition advocacy and anti-corruption

Examples from Mexico provide illustrations of competition enforcement against bid rigging in public procurement, which have benefited consumers by significant average price falls. The Mexican Competition Commission went beyond competition enforcement to engage in advocacy measures. To improve the design of the procurement procedures of IMSS, which were found to inhibit corruption and collusion, the Commission began advocacy by adopting of the OECD Guidelines to Fight Bid Rigging in Public Procurement. In recent years, the Commission has subscribed to several cooperation agreements with governmental authorities at all levels to facilitate the application of competition principles. All agreements include capacity-building on the prevention and detection of collusion and corruption, and the preparation of reports that provide recommendations to improve public procurement legislation, regulation and practices.

Source: OECD. 2014. Fighting corruption and promoting competition: Contribution from Mexico, DAF/COMP/GF/WD (2014) 50, 13 February.

57. Another relevant concern relating to competition is inappropriate payments by drug makers to hospitals and doctors in order to mislead consumers in public health distribution

[29] OECD. 2010. Round table on collusion and corruption in public procurement, DAF/COMP/GF (2010) 6, 15 October.

[30] OECD. 2014. Fighting corruption and promoting competition: Contribution from Mexico, DAF/COMP/GF/WD (2014) 50, 13 February.

systems. In some countries, physicians take on a significant role in influencing drug sales; as a result, patients are being misled into purchasing more expensive medicines. Since in some United Nations Member States commercial bribery is prohibited by competition law, competition policy can directly address corruption in the interest of consumers.

58. In 2011, the Fair Trade Commission of the Republic of Korea imposed corrective orders and surcharges of 11 billion won against six drug manufacturers for offering kickbacks. They repeatedly provided doctors, clinics and hospitals with economic incentives, through indirect means, to increase the prescription of their drugs. Such means included organizing seminars or conferences to offer free dinners, golf outings, and lecture and consultancy fees, or granting cash in the form of so-called post-market surveillance. Therefore, the pharmaceutical companies, through rebates, unduly turned consumer (patient) benefits into the medical institution's proceeds.

59. Similarly, in September 2014, the National Development and Reform Commission of China fined GlaxoSmithKline $490 million for bribery towards hospitals and doctors. Moreover, the Court issued a three-year suspended prison sentence to the former head of the company.

60. Sound policies and laws foster high ethical standards in both public and civil services. In addition to achievements of enforcement against specific restrictive business practices and advocacy for more efficient public procurement systems, competition policy can make further contributions to improved governance.

C. Coherence between competition, consumer and regulatory policies

61. The pharmaceutical industry is heavily regulated. All aspects of the life cycle of new drugs are regulated, from patent application to marketing approval, commercial exploitation, patent expiration and competition in the market, particularly with regard to generic drugs. Manufacturers, wholesalers, retailers, medical practitioners and stakeholders across the industry are subject to varying degrees of regulatory control aimed at ensuring product efficacy and safety. There is a need for coherence between competition policies and regulatory policies to enhance consumer welfare and economic efficiency.

62. In the United States, upon request of federal, state, or local government officials, the Federal Trade Commission helps legislators and regulators avoid consumer harm that would result from undue restriction of competition at each level of the pharmaceutical distribution chain. For example, the Commission has commented on direct-to-consumer advertising of prescription drugs from both consumer protection and competition perspectives. In this case, it suggested adjusting disclosure requirements to allow pharmaceutical manufacturers greater latitude in their advertising. By catalysing price and quality competition, net benefits of direct-to-consumer advertisements can be increased.[31]

63. Even with competition and a proper regulatory framework in place, consumers do not always choose the best options. Information asymmetries may contribute to this outcome. Moreover, making the wrong choice may adversely affect competition, resulting in a dysfunctional market where, despite effective competition but inadequate consumer protection, demand-side market failures may lead to consumer and structural detriment.

64. To benefit from competition, consumers must be empowered to activate it, which may be achieved through consumer education, as well as facilitating consumer access to information and enhancing the capacity of consumers to assess information correctly in order to make an optimal decision. Competition, regulatory and consumer policies should reinforce each other in achieving their common goals.

[31] See note 15.

65. In Chile, an agreement signed between the National Consumer Service, the health authority and the association of private clinics provides an example of a pro-competitive consumer policy intervention. The competition authority observed that patients were only provided with estimates of total costs, and price comparisons of different items included under treatment options were not possible, thereby leading to ex-post abusive billing by clinics. The competition authority conducted a market investigation and submitted its findings to the health authority, which took action. To address this market failure, the agreement requires clinics to inform patients of charges for medical services prior to treatment and ensures that price comparisons can be made by patients for different items. This case demonstrates the complementary nature of competition and consumer policies and the role of cooperation between relevant authorities in identifying appropriate remedies to address market failures in favour of consumers.[32]

Box 4. China: Pharmaceutical price liberalization

In China, the Government is accelerating the reform of pharmaceutical prices, the principal component of which is introducing competition. Over the years, maximum resale price maintenance has been adopted to control the drug prices. However, this method has failed to resolve issues relating to both high and low prices. In May 2014, the Department of Price Supervision of the National Development and Reform Commission announced the abolition of maximum resale price maintenance applicable to inexpensive drugs. Moreover, in accordance with the draft pharmaceutical price liberalization programme, the competition mechanism will gradually play a decisive role in resource allocation in the pharmaceutical sector. Aside from non-prescription drugs, prices of patented medicines and some heavily regulated products, including immunization, psychotropic medicines, narcotic drugs and blood products, will be liberalized initially. Ex post facto measures, such as anti-monopoly enforcement, will be strengthened to replace the price control measures by the regulator.

Source: xkb.com.cn, 2014, More radical price reform, 6 November, available in Chinese only at http://news.xkb.com.cn/caijing/2014/1106/358347.html, accessed on 20 December 2014.

IV. Issues for discussion

66. The following issues may be considered for discussion:

(a) What are the latest strategies adopted by pharmaceutical companies to stifle competition?

(b) Are there any types of unilateral conduct by producers that affect competition? In relation to this, what is the theory of "abuse of right"? How is an anticompetitive practice recognized? Is the assessment of such agreements conducted under a per se approach or the rule of reason approach?

(c) Are there anticompetitive agreements that affect competition between originator and generic drugs? In relation to this, what is the theory of harm? How is an anticompetitive practice recognized? For example, does it depend on the amount of the transaction? What happens if there is no financial transaction related to the agreement? Are such agreements always anticompetitive? Is the assessment of such agreements conducted under a per se approach or the rule of reason approach?

(d) Are there any vertical agreements at the distribution level, for example, exclusive distribution or loyalty discounts? What are the main characteristics of these

[32] TD/B/C.I/CLP/27.

agreements? Are there concerns that these agreements may reduce inter and intra brand competition? Are wholesalers vertically integrated with retailers and/or manufacturers? Are there concerns that vertical integration may reduce inter and intra brand competition?

(e) How can the objective of ensuring an adequate and affordable supply of drugs be better achieved by using competition advocacy?